DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

IMMUNALYSIS CORPORATION
JOSEPH GINETE
REGULATORY AFFAIRS SPECIALIST
829 TOWNE CENTER DR
POMONA CA 91767

May 20, 2015

Re: K143502
Trade/Device Name: Immunalysis Opiates Urine Enzyme Immunoassay
Immunalysis Opiates Urine Calibrators 300
Immunalysis Multi-Drug Controls
Immunalysis Opiates Urine Calibrators 2000
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG, DLJ, DIF
Dated: March 26, 2015
Received: March 27, 2015

Dear Mr. Joseph Ginete:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143502

Device Name
Immunalysis Opiates Urine Enzyme Immunoassay, Immunalysis Opiates Urine Calibrators 300, Immunalysis Multi-Drug Controls, and Immunalysis Opiates Urine Calibrators 2000

Indications for Use *(Describe)*

Immunalysis Opiates Urine Enzyme Immunoassay

The Immunalysis Opiates Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a dual cutoff of 300 ng/mL and 2000 ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of opiates in human urine with automated clinical chemistry analyzers. This assay is calibrated against Morphine. This in-vitro diagnostic device is for prescription use only.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.

The Immunalysis Opiates Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Immunalysis Opiates Urine Calibrators 300

The Immunalysis Opiates Urine Calibrators 300 are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Morphine. The Immunalysis Opiates Urine Calibrators 300 consists of 4 levels, with Level 1 containing 100ng/mL, Level 2 containing 300ng/mL, Level 3 containing 500ng/mL and Level 4 containing 1000ng/mL of morphine. The calibrators are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.

Immunalysis Multi-Drug Controls

The Immunalysis Multi-Drug Controls are intended for in vitro diagnostic use to monitor the performance of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methadone, Methamphetamine, Morphine, PCP, Secobarbital and Oxazepam for Immunalysis Multi-Drug Controls 1 and Benzoylecgonine, Methamphetamine and Morphine for Immunalysis Multi-Drug Controls 2. The controls are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.

Immunalysis Opiates Urine Calibrators 2000

The Immunalysis Opiates Urine Calibrators 2000 are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Morphine. The Immunalysis Opiates Urine Calibrators 2000 consists of 4 levels, with Level 1 containing 1000ng/mL, Level 2 containing 2000ng/mL, Level 3 containing 4000ng/mL and Level 4 containing 6000ng/mL of morphine. The calibrators are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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IMMUNALYSIS

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

A. Contact Information

1. Manufacturer:	Immunalysis Corporation
2. Contact Name:	Joseph Ginete
3. Contact Title:	Regulatory Affairs Specialist II
4. Address:	829 Towne Center Drive Pomona, CA 91767
5. Phone:	(909) 482-0840
6. Fax:	(909) 482-0850
7. Email:	jginete@immunalysis.com
8. Summary prepared on:	May 18, 2015

B. Device Information

1. Trade Name:	Immunalysis Opiates Urine Enzyme Immunoassay Immunalysis Opiates Urine Calibrators 300 Immunalysis Multi-Drug Controls Immunalysis Opiates Urine Calibrators 2000
2. Common Name:	Immunalysis Opiates Urine Enzyme Immunoassay Immunalysis Opiates Urine Calibrators 300 Immunalysis Multi-Drug Controls Immunalysis Opiates Urine Calibrators 2000

C. Regulatory Information

1. Device Classification:	II
2. Regulation Number:	CFR 862.3650 Opiate Test System CFR 862.3200 Clinical Toxicology Calibrator CFR 862.3280 Clinical Toxicology Control Materials
3. Panel:	Toxicology(91)
4. Product Code:	DJG DLJ DIF

D. Legally Marketed Device to Which We are Claiming Equivalence (807.92(A)(3))

1. Predicate Device: DRI® DAU Opiate Assay
   LZI Multiple Analyte Urine Drugs of Abuse Calibrators and Controls
2. Predicate Company: Microgenics
   Lin-Zhi International, Inc.
3. Predicate K Number: K011150
   K051088

E. Device Description

1. The assay consists of antibody/substrate reagent and enzyme conjugate reagent. The antibody/substrate reagent includes monoclonal antibodies to morphine, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with Sodium Azide as a preservative. The enzyme conjugate reagent includes morphine derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with Sodium Azide as a preservative.

2. All of the Immunalysis Opiates Urine Calibrators 300 are liquid and ready to use. Each contains a known concentration of a specific drug analyte as a mixture. The negative calibrator is a processed, drug-free synthetic urine matrix with sodium azide as a preservative. The Level 1, 2, 3 and 4 calibrators are prepared by spiking known concentrations of morphine into the negative calibrator matrix. These five calibrators are sold as individual bottles. The concentration of morphine in their corresponding calibrators are summarized as follows:

Table 1 Immunalysis Opiates Urine Calibrators 300

Analyte	Opiates Calibrators			
	Level 1	Level 2	Level 3	Level 4
Morphine	100ng/mL	300ng/mL	500ng/mL	1000ng/mL

3. All of the Immunalysis Multi-Drug Controls are liquid and ready to use. Each contains a known concentration of a specific drug analyte as a mixture. The negative calibrator is a processed, drug-free synthetic urine matrix with sodium azide as a preservative. The LOW Control 1, HIGH Control 1, LOW Control 2 and HIGH Control 2 are prepared by spiking known concentrations of drug analyte into the negative calibrator matrix. These four controls are sold as control sets. The concentration of drug analyte in their corresponding controls are summarized as follows:

Table 2 Immunalysis Multi-Drug Controls 1		
Analyte	Multi-Drug Controls	
	LOW Control 1	HIGH Control 1
Benzoylecgonine	112.5ng/mL	187.5ng/mL
Methadone	225ng/mL	375ng/mL
Methamphetamine	375ng/mL	625ng/mL
Morphine	225ng/mL	375ng/mL
PCP	19ng/mL	31ng/mL
Secobarbital	150ng/mL	250ng/mL
Oxazepam	150ng/mL	250ng/mL

Table 3 Immunalysis Multi-Drug Controls 2		
Analyte	Multi-Drug Controls	
	LOW Control 2	HIGH Control 2
Benzoylecgonine	225ng/mL	375ng/mL
Methamphetamine	750ng/mL	1250ng/mL
Morphine	1500ng/mL	2500ng/mL

4. All of the Immunalysis Opiates Urine Calibrators 2000 are liquid and ready to use. Each contains a known concentration of a specific drug analyte. The negative calibrator is a processed, drug-free synthetic urine matrix with sodium azide as a preservative. The Level 1, 2, 3 and 4 calibrators are prepared by spiking known concentrations of morphine into the negative calibrator matrix. These five calibrators are sold as individual bottles. The concentration of morphine in the corresponding calibrators are summarized as follows:

Table 4 Immunalysis Opiates Urine Calibrators 2000				
Analyte	Opiates Calibrators			
	Level 1	Level 2	Level 3	Level 4
Morphine	1000ng/mL	2000ng/mL	4000ng/mL	6000ng/mL

F. Intended Use

1. The Immunalysis Opiates Urine Enzyme Immunoassay is a homogeneous enzyme immunoassay with a dual cutoff of 300ng/mL and 2000ng/mL. The assay is intended for use in laboratories for the qualitative and semi-quantitative analysis of opiates in human urine with automated clinical chemistry analyzers. This assay is calibrated against Morphine. This in-vitro diagnostic device is for prescription use only.
   The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC-MS or permitting laboratories to establish quality control procedures.
   The Immunalysis Opiates Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

2. The Immunalysis Opiates Urine Calibrators 300 are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Morphine. The Immunalysis Opiates Urine Calibrators 300 consists of 4 levels, with Level 1 containing 100ng/mL, Level 2 containing 300ng/mL, Level 3 containing 500ng/mL and Level 4 containing 1000ng/mL of morphine. The calibrators are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.

   The Immunalysis Multi-Drug Controls are intended for in vitro diagnostic use to monitor the performance of assays for the analytes currently listed in the package insert: Benzoylecgonine, Methadone, Methamphetamine, Morphine, PCP, Secobarbital and Oxazepam for Immunalysis Multi-Drug Controls 1 and Benzoylecgonine, Methamphetamine and Morphine for Immunalysis Multi-Drug Controls 2. The controls are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.

   The Immunalysis Opiates Urine Calibrators 2000 are intended for in vitro diagnostic use for the calibration of assays for the analytes currently listed in the package insert: Morphine. The Immunalysis Opiates Urine Calibrators 2000 consists of 4 levels, with Level 1 containing 1000ng/mL, Level 2 containing 2000ng/mL, Level 3 containing 4000ng/mL and Level 4 containing 6000ng/mL of morphine. The calibrators are designed for prescription use with homogenous enzyme immunoassays on automated clinical chemistry analyzers.

G. Comparison of the new device with the predicate device

Item	**Opiates Assay** K011150	**Immunalysis Opiates Urine EIA**
Intended Use	For the qualitative and semi-quantitative determination of the presence of opiates in human urine at a cutoff of 300ng/mL and 2000ng/mL	For the qualitative and semi-quantitative determination of the presence of opiates in human urine at a cutoff of 300ng/mL and 2000ng/mL
Type of Product	Analytical Reagents	Analytical Reagents
Measured Analytes	Opiates	Opiates
Test Matrix	Urine	Urine
Cutoff Levels	300ng/mL and 2000ng/mL of Morphine	300ng/mL and 2000ng/mL of Morphine
Test System	Homogeneous Enzyme Immunoassay	Homogeneous Enzyme Immunoassay (EIA)
Materials	Antibody/Substrate Reagents and Enzyme Labeled Conjugate	Antibody/Substrate Reagents and Enzyme Labeled Conjugate
Mass Spectroscopy Confirmation	Required for preliminary positive analytical results	Required for preliminary positive analytical results
Antibody	Monoclonal antibody to Opiates	Monoclonal antibody to Opiates
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date

Item	**LZI Multiple Analyte** K051088	**Immunalysis Opiates Urine Calibrators 300**
Analyte	benzoylecgonine, d-methamphetamine, methadone, morphine, oxazepam, secobarbital, phencyclidine, propoxyphene	Morphine
Matrix	Urine	Same
Calibrator Levels	5 Levels – See Table 5 Below	5 Levels (Negative and Level 1, 2, 3 and 4) - See Device Description Table 1
Storage	2 – 8°C until expiration date	Same

Item	**LZI Multiple Analyte** K051088	**Immunalysis Multi-Drug Controls**
Analyte	benzoylecgonine, d-methamphetamine, methadone, morphine, oxazepam, secobarbital, phencyclidine, propoxyphene	benzoylecgonine, methadome, methamphetamine, morphine, PCP, secobarbital, oxazepam
Matrix	Urine	Urine
Control Levels	2 Levels – See Table 5 Below	4 Levels (LOW Control 1, HIGH Control 1, LOW Control 2 and HIGH Control 2) – See Device Description Table 2 and Table 3
Storage	2 – 8°C until expiration date	2 – 8°C until expiration date

Item	**LZI Multiple Analyte** K051088	**Immunalysis Opiates Urine Calibrators 2000**
Analyte	benzoylecgonine, d-methamphetamine, methadone, morphine, oxazepam, secobarbital, phencyclidine, propoxyphene	Morphine
Matrix	Urine	Same
Calibrator Levels	5 Levels – See Table 5 Below	5 Levels (Negative and Level 1, 2, 3 and 4) - See Device Description Table 4
Storage	2 – 8°C until expiration date	Same

Table 5 LZI Multiple Analyte Urine Drugs of Abuse Calibrators and Controls

Analyte	Multiple Analyte Calibrators				Multiple Analyte Controls	
	Low	Cutoff	Intermediate	High	Level 1	Level 2
d-Methamphetamine	250ng/mL	500ng/mL	750ng/mL	1000ng/mL	375ng/mL	625ng/mL
Morphine	1000ng/mL	2000ng/mL	4000ng/mL	6000ng/mL	1500ng/mL	2500ng/mL
Phencyclidine	12.5ng/mL	25ng/mL	50ng/mL	100ng/mL	18ng/mL	35ng/mL
Benzoylecgonine	75ng/mL	150ng/mL	300ng/mL	1000ng/mL	110ng/mL	190ng/mL
Oxazepam	100ng/mL	200ng/mL	500ng/mL	1000ng/mL	100ng/mL	300ng/mL
Secobarbital	100ng/mL	200ng/mL	500ng/mL	1000ng/mL	100ng/mL	300ng/mL
Propoxyphene	150ng/mL	300ng/mL	600ng/mL	1000ng/mL	225ng/mL	375ng/mL
Methadone	150ng/mL	300ng/mL	600ng/mL	1000ng/mL	225ng/mL	375ng/mL

H. The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Opiates Urine Enzyme Immunoassay to the predicate:

1. Precision/Cutoff Characterization – Study was performed for 20 days, 2 runs per day in duplicate (N=80) on concentration of ±25%, ±50%, ±75%, and ±100% of the cutoff. The study verified that the cutoff serves as a boundary between a negative and positive interpretation of a qualitative result. In addition, it also verified the product performance relative to the ability of the device to produce the same value during repeated measurements. The instruments used for this was a Beckman Coulter AU 400e.
    a. The following is a summary table of the Qualitative Analysis for the 300ng/mL cutoff test data results.

Table 6- Qualitative Analysis (for 300ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
75	-75%	80	80 Negative
150	-50%	80	80 Negative
225	-25%	80	80 Negative
300	Cutoff	80	37 Negative/43 Positive
375	+25%	80	80 Positive
450	+50%	80	80 Positive
525	+75%	80	80 Positive
600	+100%	80	80 Positive

    b. The following is a summary table of the Qualitative Analysis for the 2000ng/mL cutoff test data results.

Table 7 - Qualitative Analysis (for 2000ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
500	-75%	80	80 Negative
1000	-50%	80	80 Negative
1500	-25%	80	80 Negative
2000	Cutoff	80	42 Negative/38 Positive
2500	+25%	80	80 Positive
3000	+50%	80	80 Positive
3500	+75%	80	80 Positive
4000	+100%	80	80 Positive

    c. The following is a summary table of the Semi-Quantitative Analysis for the 300ng/mL cutoff test data results.

Table 8 - Semi-Quantitative Analysis (for 300ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
75	-75%	80	80 Negative
150	-50%	80	80 Negative
225	-25%	80	80 Negative
300	Cutoff	80	20 Negative/60 Positive
375	+25%	80	80 Positive

Table 8 - Semi-Quantitative Analysis (for 300ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
450	+50%	80	80 Positive
525	+75%	80	80 Positive
600	+100%	80	80 Positive

d. The following is a summary table of the Semi-Quantitative Analysis for the 2000ng/mL cutoff test data results.

Table 9 - Semi-Quantitative Analysis (for 2000ng/mL cutoff)			
Concentration (ng/mL)	% of cutoff	# of determinations	Result
0	-100%	80	80 Negative
500	-75%	80	80 Negative
1000	-50%	80	80 Negative
1500	-25%	80	80 Negative
2000	Cutoff	80	41 Negative/39 Positive
2500	+25%	80	80 Positive
3000	+50%	80	80 Positive
3500	+75%	80	80 Positive
4000	+100%	80	80 Positive

2. Specificity and Cross-Reactivity – Structurally similar compounds were spiked into drug free urine at levels that will yield a result that is equivalent to the cutoffs. The study verified assay performance relative to the ability of the device to exclusively determine certain drugs. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The qualitative result summary table for the 300ng/mL cutoffs is outlined below:

Table 10 - Structurally Related Compounds (for 300ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
6-Acetylmorphine	150	POS	200.0
Codeine	200	POS	150.0
Dihydrocodeine	150	POS	200.0
Ethylmorphine	300	POS	100.0
Heroin	300	POS	100.0
Hydrocodone	400	POS	75.0
Levorphanol	8,000	POS	3.8
Morphine-3-Glucuronide	200	POS	150.0
Morphine-6-Glucuronide	100	POS	300.0
Hydromorphone	700	POS	42.9
Nalorphine	2,000	POS	15.0
Naloxone	60,000	POS	0.5
Norcodeine	25,000	POS	1.2
Normorphine	25,000	POS	1.2
Oxycodone	10,000	POS	3.0
Oxymorphone	20,000	POS	1.5

b. The qualitative result summary table for the 2000ng/mL cutoff is outlined below:

Table 11 - Structurally Related Compounds (for 2000ng/mL cutoff) - Qualitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
6-Acetylmorphine	2,000	POS	100.0
Codeine	2,000	POS	100.0
Dihydrocodeine	600	POS	333.3
Ethylmorphine	2,000	POS	100.0
Heroin	4,000	POS	50.0
Hydrocodone	4,000	POS	50.0
Levorphanol	100,000	POS	2.0
Morphine-3-Glucuronide	2,000	POS	100.0
Morphine-6-Glucuronide	600	POS	333.3
Hydromorphone	8,000	POS	25.0
Nalorphine	28,000	POS	7.1
Naloxone	500,000	POS	0.4
Norcodeine	300,000	POS	0.7
Normorphine	300,000	POS	0.7
Oxycodone	100,000	POS	2.0
Oxymorphone	200,000	NEG	1.0

c. The semi-quantitative result summary table for the 300ng/mL cutoff is outlined below:

Table 12 - Structurally Related Compounds (for 300ng/mL cutoff) – Semi-Quantitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
6-Acetylmorphine	150	POS	200.0
Codeine	200	NEG	150.0
Dihydrocodeine	150	POS	200.0
Ethylmorphine	300	POS	100.0
Heroin	300	POS	100.0
Hydrocodone	400	POS	75.0
Levorphanol	8,000	POS	3.8
Morphine-3-Glucuronide	200	POS	150.0
Morphine-6-Glucuronide	100	POS	300.0
Hydromorphone	700	POS	42.9
Nalorphine	2,000	POS	15.0
Naloxone	60,000	POS	0.5
Norcodeine	25,000	POS	1.2
Normorphone	25,000	POS	1.2
Oxycodone	10,000	POS	3.0
Oxymorphone	20,000	POS	1.5

d. The semi-quantitative result summary table for the 2000ng/mL cutoff is outlined below:

Table 13 - Structurally Related Compounds (for 2000ng/mL cutoff) – Semi-Quantitative			
Compound	Concentration Tested (ng/mL)	Result	Cross-Reactivity (%)
6-Acetylmorphine	2,000	POS	100.0
Codeine	2,000	POS	100.0
Dihydrocodeine	600	POS	333.3
Ethylmorphine	2,000	POS	100.0
Heroin	4,000	POS	50.0
Hydrocodone	4,000	POS	50.0
Levorphanol	100,000	POS	2.0
Morphine-3-Glucuronide	2,000	POS	100.0
Morphine-6-Glucuronide	600	POS	333.3
Hydromorphone	8,000	POS	25.0
Nalorphine	28,000	POS	7.1
Naloxone	500,000	POS	0.4
Norcodeine	300,000	POS	0.7
Normorphine	300,000	POS	0.7
Oxycodone	100,000	POS	2.0
Oxymorphone	200,000	NEG	1.0

3. Interference – Structurally non-similar compounds, endogenous compounds, the effect of pH and the effect of specific gravity was evaluated by spiking the potential interferents into drug free urine containing morphine at ±25% of the cutoffs. Boric Acid and Riboflavin caused a false negative response at the concentrations tested. All other potential interferents analyzed verified that assay performance is unaffected by externally ingested compounds or an internally existing physiological condition. The instrument used for this test was a Beckman Coulter AU 400e.
    a. The following is a summary table of the structurally non-similar compounds for the 300ng/mL cutoff:

Table 14 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (225ng/mL)**		**+25% Cutoff (375ng/mL)**	
		Result	Interference?	Result	Interference?
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicylic Acid	500,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
Amphetamine	500,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No
Amobarbital	100,000	Negative	No	Positive	No
Benzoylecgonine	500,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No

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Table 14 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (225ng/mL)**		**+25% Cutoff (375ng/mL)**	
		Result	Interference?	Result	Interference?
Buprion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No
Carbamazepine	100,000	Negative	No	Positive	No
Cocaine	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Chloropromazine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
N-Desmethyltapentadol	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Diphenhydramine	500,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
Ephedrine	100,000	Negative	No	Positive	No
EDDP	100,000	Negative	No	Positive	No
Ethyl-glucuronide	100,000	Negative	No	Positive	No
Fenfluramine	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
Ibuprofen	100,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No
Meperidine	50,000	Negative	No	Positive	No
Methadone	500,000	Negative	No	Positive	No
Methaqualone	100,000	Negative	No	Positive	No
Methamphetamine	500,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
Norbuprenorphine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Nortryptyline	100,000	Negative	No	Positive	No
Norpropoxyphene	100,000	Negative	No	Positive	No

Table 14 - Structurally Non-Similar Compounds (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (225ng/mL)		+25% Cutoff (375ng/mL)	
		Result	Interference?	Result	Interference?
Oxazepam	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No
Pentazocine	100,000	Negative	No	Positive	No
Phencyclidine	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Phenylpropanolamine	500,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
(-)Pseudoephedrine	100,000	Negative	No	Positive	No
(+)Pseudoephedrine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
Protryptyline	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sufentanil	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
11-nor-9 carboxy THC	100,000	Negative	No	Positive	No
Tramadol	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No

b. The following is a summary table of the structurally non-similar compounds for the 2000ng/mL cutoff:

Table 15 - Structurally Non-Similar Compounds (for 2000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	-25% Cutoff (1500ng/mL)		+25% Cutoff (2500ng/mL)	
		Result	Interference?	Result	Interference?
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	Negative	No	Positive	No
Acetaminophen	500,000	Negative	No	Positive	No
Acetylsalicylic Acid	500,000	Negative	No	Positive	No
Alprazolam	100,000	Negative	No	Positive	No
Amphetamine	500,000	Negative	No	Positive	No
Amitriptyline	100,000	Negative	No	Positive	No
Amobarbital	100,000	Negative	No	Positive	No
Benzoylecgonine	500,000	Negative	No	Positive	No
Benzylpiperazine	100,000	Negative	No	Positive	No
Bromazepam	100,000	Negative	No	Positive	No
Buprenorphine	100,000	Negative	No	Positive	No
Buprion	100,000	Negative	No	Positive	No
Butabarbital	100,000	Negative	No	Positive	No
Caffeine	500,000	Negative	No	Positive	No

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Table 15 - Structurally Non-Similar Compounds (for 2000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (1500ng/mL)**		**+25% Cutoff (2500ng/mL)**	
		Result	Interference?	Result	Interference?
Carbamazepine	100,000	Negative	No	Positive	No
Cocaine	100,000	Negative	No	Positive	No
Clomipramine	100,000	Negative	No	Positive	No
Clonazepam	100,000	Negative	No	Positive	No
Chloropromazine	100,000	Negative	No	Positive	No
Cyclobenzaprine	100,000	Negative	No	Positive	No
N-Desmethyltapentadol	100,000	Negative	No	Positive	No
Desipramine	100,000	Negative	No	Positive	No
Dextromethorphan	100,000	Negative	No	Positive	No
Diazepam	100,000	Negative	No	Positive	No
Diphenhydramine	500,000	Negative	No	Positive	No
Doxepin	100,000	Negative	No	Positive	No
Ephedrine	100,000	Negative	No	Positive	No
EDDP	100,000	Negative	No	Positive	No
Ethyl-glucuronide	100,000	Negative	No	Positive	No
Fenfluramine	100,000	Negative	No	Positive	No
Fluoxetine	100,000	Negative	No	Positive	No
Flurazepam	100,000	Negative	No	Positive	No
Hexobarbital	100,000	Negative	No	Positive	No
Ibuprofen	100,000	Negative	No	Positive	No
Imipramine	100,000	Negative	No	Positive	No
Ketamine	100,000	Negative	No	Positive	No
Lidocaine	100,000	Negative	No	Positive	No
LSD	100,000	Negative	No	Positive	No
Lorazepam	100,000	Negative	No	Positive	No
Maprotiline	100,000	Negative	No	Positive	No
MDEA	100,000	Negative	No	Positive	No
MDA	100,000	Negative	No	Positive	No
MDMA	100,000	Negative	No	Positive	No
Meperidine	100,000	Negative	No	Positive	No
Methadone	500,000	Negative	No	Positive	No
Methaqualone	100,000	Negative	No	Positive	No
Methamphetamine	500,000	Negative	No	Positive	No
Meprobamate	100,000	Negative	No	Positive	No
Naltrexone	100,000	Negative	No	Positive	No
Nitrazepam	100,000	Negative	No	Positive	No
Norbuprenorphine	100,000	Negative	No	Positive	No
Nordiazepam	100,000	Negative	No	Positive	No
Nortryptyline	100,000	Negative	No	Positive	No
Norpropoxyphene	100,000	Negative	No	Positive	No
Oxazepam	100,000	Negative	No	Positive	No
Pentobarbital	100,000	Negative	No	Positive	No
Phenobarbital	100,000	Negative	No	Positive	No

Table 15 - **Structurally Non-Similar Compounds** (for 2000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (1500ng/mL)**		**+25% Cutoff (2500ng/mL)**	
		Result	Interference?	Result	Interference?
Pentazocine	100,000	Negative	No	Positive	No
Phencyclidine	100,000	Negative	No	Positive	No
Phentermine	100,000	Negative	No	Positive	No
Phenylpropanolamine	500,000	Negative	No	Positive	No
PMA	100,000	Negative	No	Positive	No
(-)Pseudoephedrine	100,000	Negative	No	Positive	No
(+)Pseudoephedrine	100,000	Negative	No	Positive	No
Phenytoin	100,000	Negative	No	Positive	No
Protryptyline	100,000	Negative	No	Positive	No
Ranitidine	100,000	Negative	No	Positive	No
Ritalinic Acid	100,000	Negative	No	Positive	No
Secobarbital	100,000	Negative	No	Positive	No
Sufentanil	100,000	Negative	No	Positive	No
Temazepam	100,000	Negative	No	Positive	No
11-nor-9 carboxy THC	100,000	Negative	No	Positive	No
Tramadol	100,000	Negative	No	Positive	No
Trimipramine	100,000	Negative	No	Positive	No
Venlafaxine	100,000	Negative	No	Positive	No

c. The following is a summary table of the endogenous compounds results for the 300ng/mL cutoff:

Table 16 - **Endogenous Compounds** (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (225ng/mL)**		**+25% Cutoff (375ng/mL)**	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	1.5 g/dL	Negative	No	Positive	No
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No
γ-Globulin	0.5 g/dL	Negative	No	Positive	No
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.300 g/dL	Negative	No	Positive	No
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	**0.0075 g/dL**	Negative	No	**Negative**	**Yes**
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

d. Riboflavin interferes with the assay and can cause a falsely low test result. This limitation has been added to the labeling regarding this compound.

e. The following is a summary table of the endogenous compounds results for the 2000ng/mL cutoff:

Table 17 - Endogenous Compounds (for 2000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (1500ng/mL)**		**+25% Cutoff (2500ng/mL)**	
		Result	Interference?	Result	Interference?
Acetone	1.0 g/dL	Negative	No	Positive	No
Ascorbic Acid	1.5 g/dL	Negative	No	Positive	No
Bilirubin	0.002 g/dL	Negative	No	Positive	No
Creatinine	0.5 g/dL	Negative	No	Positive	No
Ethanol	1.0 g/dL	Negative	No	Positive	No
Galactose	0.01 g/dL	Negative	No	Positive	No
γ-Globulin	0.5 g/dL	Negative	No	Positive	No
Glucose	2.0 g/dL	Negative	No	Positive	No
Hemoglobin	0.300 g/dL	Negative	No	Positive	No
Human Serum Albumin	0.5 g/dL	Negative	No	Positive	No
Oxalic Acid	0.1 g/dL	Negative	No	Positive	No
Riboflavin	0.0075 g/dL	Negative	No	Positive	No
Sodium Azide	1% w/v	Negative	No	Positive	No
Sodium Chloride	6.0 g/dL	Negative	No	Positive	No
Sodium Fluoride	1% w/v	Negative	No	Positive	No
Urea	6.0 g/dL	Negative	No	Positive	No

f. The following is a summary table of the Boric Acid for the 300ng/mL cutoff results:

Table 18 - Boric Acid (for 300ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (225ng/mL)**		**+25% Cutoff (375ng/mL)**	
		Result	Interference?	Result	Interference?
Boric Acid	**1% w/v**	Negative	No	**Negative**	**Yes**

g. The following is a summary table of the Boric Acid for the 2000ng/mL cutoff results:

Table 19- Boric Acid (for 2000ng/mL cutoff)					
Compound	Concentration Tested (ng/mL)	**-25% Cutoff (1500ng/mL)**		**+25% Cutoff (2500ng/mL)**	
		Result	Interference?	Result	Interference?
Boric Acid	**1% w/v**	Negative	No	**Negative**	**Yes**

h. Boric Acid interferes with the assay and can cause a falsely low test result. This limitation has been added to the labeling regarding this compound.

i. The following is a summary table of the effect of pH results for the 300ng/mL cutoff:

Table 20 - Effect of pH (for 300ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (225ng/mL)**		**+25% Cutoff (375ng/mL)**	
		Result	Interference?	Result	Interference?
pH	3.0	Negative	No	Positive	No
pH	4.0	Negative	No	Positive	No
pH	5.0	Negative	No	Positive	No
pH	6.0	Negative	No	Positive	No
pH	7.0	Negative	No	Positive	No
pH	8.0	Negative	No	Positive	No
pH	9.0	Negative	No	Positive	No
pH	10.0	Negative	No	Positive	No
pH	11.0	Negative	No	Positive	No

j. The following is a summary table of the effect of the pH results for the 2000ng/mL cutoff:

Table 21 - Effect of pH (for 2000ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (1500ng/mL)**		**+25% Cutoff (2500ng/mL)**	
		Result	Interference?	Result	Interference?
pH	3.0	Negative	No	Positive	No
pH	4.0	Negative	No	Positive	No
pH	5.0	Negative	No	Positive	No
pH	6.0	Negative	No	Positive	No
pH	7.0	Negative	No	Positive	No
pH	8.0	Negative	No	Positive	No
pH	9.0	Negative	No	Positive	No
pH	10.0	Negative	No	Positive	No
pH	11.0	Negative	No	Positive	No

k. The following is a summary table of the effect of specific gravity result for the 300ng/mL cutoff:

Table 22 - Effect of Specific Gravity (for 300ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (225ng/mL)**		**+25% Cutoff (375ng/mL)**	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	Negative	No	Positive	No
Specific Gravity	1.002	Negative	No	Positive	No
Specific Gravity	1.005	Negative	No	Positive	No
Specific Gravity	1.010	Negative	No	Positive	No
Specific Gravity	1.015	Negative	No	Positive	No
Specific Gravity	1.020	Negative	No	Positive	No
Specific Gravity	1.025	Negative	No	Positive	No
Specific Gravity	1.030	Negative	No	Positive	No

l. The following is a summary table of the effect of specific gravity result for the 2000ng/mL cutoff:

Table 23 - Effect of Specific Gravity (for 2000ng/mL cutoff)					
Test Parameter	Value	**-25% Cutoff (1500ng/mL)**		**+25% Cutoff (2500ng/mL)**	
		Result	Interference?	Result	Interference?
Specific Gravity	1.000	Negative	No	Positive	No
Specific Gravity	1.002	Negative	No	Positive	No
Specific Gravity	1.005	Negative	No	Positive	No
Specific Gravity	1.010	Negative	No	Positive	No
Specific Gravity	1.015	Negative	No	Positive	No
Specific Gravity	1.020	Negative	No	Positive	No
Specific Gravity	1.025	Negative	No	Positive	No
Specific Gravity	1.030	Negative	No	Positive	No

4. Linearity/ Recovery – A drug free urine pool was spiked with a high concentration of the target analyte as high value specimen. Additional pools were made by serially diluting the high value specimen. The study verified assay linearity in the semi-quantitative mode. The instrument used for this test was a Beckman Coulter AU 400e.

   a. The following is a summary table of the linearity/recovery for the 300ng/mL cutoff:

Table 24 - Linearity/ Recovery – 300ng/mL		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
100	91.6	91.6
200	203.7	101.8
300	292.8	97.6
400	410.1	102.5
500	488.1	97.6
600	651.1	108.5
700	759.4	108.5
800	840.6	105.1
900	906.5	100.7
1000	1024.1	102.4
1100	1069.9	97.3

b. The following is a summary table of the linearity/recovery for the 2000ng/mL cutoff:

Table 25 - Linearity/ Recovery – 2000ng/mL		
Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
600	635.0	105.8
1200	1295.2	107.9
1800	1750.9	97.3
2000	2079.0	104.0
2400	2231.1	93.0
3000	3142.9	104.8
3600	3852.7	107.0
4200	4465.4	106.3
4800	5101.8	106.3
5400	5789.0	107.2
6000	5972.3	99.5
6600	6637.7	100.6

5. Method Comparison – Unaltered, anonymous and discarded clinical urine samples obtained from clinical testing laboratories were analyzed with the test device. The study verified that the product performance can be verified by Mass Spectrometry. The instrument used for this test was a Beckman Coulter AU 400e and an Agilent 6430 Liquid Chromatography Tandem Mass Spectrometry.

a. The following is a comparison table of qualitative assay performance for the 300ng/mL cutoff:

Table 26 - Method Comparison (for 300ng/mL cutoff) - Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	1
	(-)	0	39

b. The following is a summary table of qualitative assay performance for the 300ng/mL cutoff:

Table 27 - Assay Performance verified by LC/MS – 300ng/mL Cutoff – Qualitative					
Type	Opiates Concentration				Agreement (%)
	< 150ng/mL	150 ~ 299 ng/mL	300 ~ 450 ng/mL	> 450 ng/mL	
Qualitative/ Positive	0	1	5	35	98%
Qualitative/ Negative	36	3	0	0	100%

c. The following is a summary table of qualitative discordant results for the 300ng/mL cutoff

Table 28 - Discordant Result Summary – 300ng/mL Cutoff – Qualitative		
Qualitative Results 300ng Cutoff	LC/MS Confirmation	
Test Device	Qualitative	Total Opiate Concentration (ng/mL)
Positive	**Negative**	**200**

d. The following is a comparison table of qualitative assay performance for the 2000ng/mL cutoff:

Table 29 - Method Comparison (for 2000ng/mL cutoff) - Qualitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

e. The following is a summary table of qualitative assay performance for the 2000ng/mL cutoff:

Table 30 - Assay Performance verified by LC/MS – 2000ng/mL Cutoff - Qualitative					
Type	Opiates Concentration				Agreement (%)
	<1000ng/mL	1000~1999ng/mL	2000~3000ng/mL	>3000ng/mL	
Qualitative/ Positive	0	0	5	35	100%
Qualitative/ Negative	36	4	0	0	100%

f. The following is a comparison table of semi-quantitative assay performance for 300ng/mL:

Table 31 - Method Comparison (for 300ng/mL cutoff) – Semi-Quantitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

g. The following is a summary table of semi-quantitative assay performance for the 300ng/mL cutoff:

Table 32 - Assay Performance verified by LC/MS – 300ng/mL Cutoff – Semi-Quantitative					
Type	Opiates Concentration				Agreement (%)
	< 150ng/mL	150 ~ 299 ng/mL	300 ~ 450 ng/mL	> 450 ng/mL	
Semi-Quantitative/ Positive	0	0	5	35	100%
Semi-Quantitative / Negative	36	4	0	0	100%

h. The following is a comparison table of semi-quantitative assay performance for the 2000ng/mL cutoff:

Table 33 - Method Comparison (for 2000ng/mL cutoff) – Semi-Quantitative

		LC/MS Confirmation	
		(+)	(-)
Test Device	(+)	40	0
	(-)	0	40

i. The following is a summary table of semi-quantitative assay performance for the 2000ng/mL cutoff:

Table 34 - Assay Performance verified by LC/MS – 2000ng/mL Cutoff – Semi-Quantitative					
Type	Opiates Concentration				Agreement (%)
	<1000ng/mL	1000~1999ng/mL	2000~3000ng/mL	>3000ng/mL	
Semi-Quantitative/ Positive	0	0	5	35	100%
Semi-Quantitative / Negative	36	4	0	0	100%

6. Stability –
    a. A closed accelerated stability study was performed on reagents at 25ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 1 year for reagents. The instruments used for this test was a Beckman Coulter AU 400e.
    b. An open/on-board stability study was performed on reagents to establish expiration dating when reagents are opened and stored on board the instrument at 2ºC to 8ºC. The stability study supported an initial open vial expiration date of 28 days. The instrument used for this test was a Beckman Coulter AU 400e.
    c. Real time stability studies are ongoing

7. Calibrator and Control Analytical Performance – Immunalysis Opiates Urine Calibrators 300
    a. Opiates Calibrator Traceability – all components of the calibrators have been traced to a commercially available standard solution.
    b. Opiates Calibrator Closed Vial Stability – An accelerated closed vial stability study was performed at 25ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 12 months. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All calibrator levels (1, 2, 3, and 4) for Morphine were within specifications for Day 0, 8, 16, 24, 32, and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.
    c. Opiates Calibrator Open Vial Stability – An accelerated open vial stability study was performed at 5ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 60 days. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All calibrator levels (1, 2, 3, and 4) for Morphine were within specifications for Day 0, 19, 26, 33, 41, and 60. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.
    d. Opiates Calibrator Value Assignment – Calibrators are manufactured and are tested by mass spectrometry. If any of the analytes are not of the acceptable range, then the calibrators are adjusted and re-tested. Values

are assigned to the calibrators once the mass spectrometry results are within the acceptable ranges.

8. Calibrator and Control Analytical Performance – Immunalysis Multi-Drug Controls
    a. Multi-Drug Control Traceability – all components of the controls have been traced to a commercially available standard solution.
    b. Multi-Drug Control Closed Vial Stability – An accelerated closed vial stability study was performed at 25ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 12 months. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All control levels (Low Control 1 and 2 and High Control 1 and 2) for Benzoylegonine, Methadone, Methamphetamine, Morphine, PCP, Secobarbital and Oxazepam were within specifications for Day 0, 8, 16, 24, 32, and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.
    c. Multi-Drug Control Open Vial Stability – An open vial stability study was performed at 5ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 60 days. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All control levels (Low Control 1 and 2 and High Control 1 and 2) for Benzoylegonine, Methadone, Methamphetamine, Morphine, PCP, Secobarbital and Oxazepam were within specifications for Day 0, 19, 26, 33, 41, and 60. This stability study was performed to establish initial expiration dating.
    d. Multi-Drug Control Value Assignment – Controls are manufactured and are tested by mass spectrometry. If any of the analytes are not of the acceptable range, then the controls are adjusted and re-tested. Values are assigned to the controls once the mass spectrometry results are within the acceptable ranges.
9. Calibrator Analytical Performance – Immunalysis Opiates Urine Calibrators 2000
    a. Opiates Urine Calibrators Traceability – all components of the calibrators have been traced to a commercially available standard solution.
    b. Opiates Urine Calibrators Closed Vial Stability – An accelerated stability study was performed at 25ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 12 months. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All calibrator levels (1, 2, 3, and 4) for Morphine were within specifications for Day 0, 8, 16, 24, 32, and 40. This accelerated stability study was performed to establish initial expiration dating. Real time stability studies are ongoing.
    c. Opiates Urine Calibrators Open Vial Stability – A stability study was performed at 5ºC to establish the initial expiration dating. The stability study supported an initial expiration date of 60 days. The instrument used for this test was an Agilent 1200 Series Liquid Chromatograph coupled to Agilent 6410 Tandem Mass Spectrometer. All calibrator levels (1, 2, 3, and 4) for Morphine were within specifications for Day 0, 19, 26, 33, 41,

and 60. This stability study was performed to establish initial expiration dating.

d. Opiates Urine Calibrators Value Assignment - Calibrators are manufactured and are tested by mass spectrometry. If any of the analytes are not of the acceptable range, then the calibrators is adjusted and re-tested. Values are assigned to the calibrators once the mass spectrometry results are within the acceptable ranges.

I. Conclusion

The information provided in this pre-market notification demonstrates that the Immunalysis Opiates Urine Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its general intended use.